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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/088,970	YIP ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,12,20 and 84-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 8, 12, 20 and 84-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to the Amendment

The Amendment filed on 03/01/2007 in response to the previous Non-Final Office Action (9/01/2006) is acknowledged and has been entered.

Claims 1, 8, 12, 20 and 84-94 are currently pending and under consideration.

Rejections Withdrawn:

Applicant's arguments, see page 2, filed on 3/01/200, with respect to the rejection of claims 1, 8, 12, 20 and 84-94 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement have been fully considered and are persuasive. Thus, the rejection has been withdrawn.

Rejections Maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8, 12, 20 and 84-94 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of diagnosing prostate cancer versus benign prostate hyperplasia, the method comprising: (i) obtaining from a subject suspected of having either prostate cancer or benign prostate hyperplasia a sample containing a plurality of prostate related protein markers having apparent molecular weights below 10,000 Da, wherein the sample is from seminal plasma; (ii) determining by mass spectroscopy the intensity of the signal for mass/charge ratios of the plurality of protein markers in the sample, the protein having an apparent molecular weight of less than 10,000 Da; (iii) comparing the intensity of the signal for mass/charge ratios of

the plurality of protein markers having apparent molecular weight markers of less than 10,000 obtained from step (ii) with the intensity of the signal for mass/charge ratios of the plurality of protein markers having apparent molecular weight markers of less than 10,000 from a control sample where the control sample originates from benign prostate hyperplasia; and (iv) determining whether the comparisons of intensity of the signal for mass/charge ratios obtained in step (iii) is a diagnosis of prostate cancer versus benign prostate hyperplasia, wherein a sample from seminal plasma having a protein characterized by molecular weight of 2776 Da, 4423 Da, 4480 Da, 5753 Da, 6098 Da, 6270 Da, 6998 Da, 7843 Da, 8030 Da, 8240 Da and 8714 Da is a diagnostic of prostate cancer, does not reasonably provide enablement for a method of diagnosing prostate cancer versus benign prostate hyperplasia, the method comprising : (i) obtaining from a subject a sample containing a plurality of prostate related protein markers having apparent molecular weights below 10,000 Da, wherein the sample is selected from the group consisting of prostate tissue, blood, serum, semen, seminal fluid or seminal plasma; (ii) determining by mass spectroscopy a test amount of the plurality of protein markers in the sample, the protein having an apparent molecular weight of less than 10,000 Da; (iii) comparing the test amount of the plurality of protein markers having apparent molecular weight markers of less than 10,000 from a control sample where the control sample originates from benign prostate hyperplasia; and (iv) determining whether the test amount is a diagnostic amount consistent with a diagnosis of prostate cancer versus benign prostate hyperplasia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining

whether undue experimentation is required include: (1) the nature of the invention, (2) the relative skill of those in the art, (3) the breadth of the claims, (4) the amount or direction or guidance presented, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the state of the prior art, and (8) the predictability or unpredictability of the art.

Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406) Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

The nature of the invention

The claims are drawn to a method of diagnosing prostate cancer versus benign prostate hyperplasia, wherein a sample containing a plurality of proteins having apparent molecular weights below 10,000 Da is compared to a control sample containing a plurality of proteins having apparent molecular weights below 10,000 Da where the control sample originates from benign prostate hyperplasia. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Level of skill in the art

The level of skill in the art is deemed to be high, generally that of a PhD or MD.

The breadth of the claims

Applicants broadly claim a a method of diagnosing prostate cancer versus benign prostate hyperplasia, the method comprising : (i) obtaining from a subject a sample containing a plurality of prostate related protein markers having apparent molecular weights below 10,000 Da, wherein the sample is selected from the group consisting of prostate tissue, blood, serum, semen, seminal fluid or seminal plasma; (ii) determining by mass spectroscopy a test amount of the plurality of protein markers in the sample, the protein having an apparent molecular weight of less than 10,000 Da; (iii) comparing the test amount of the plurality of protein markers having apparent molecular weight markers of less than 10,000 from a control sample where the control sample originates from benign prostate hyperplasia; and (iv) determining whether the test amount is a diagnostic amount consistent with a diagnosis of prostate cancer versus benign prostate hyperplasia. As such, the "test amount" is used to determining whether one suffers from prostate cancer or benign prostate hyperplasia.

Guidance in the specification and Working Examples

The specification teaches that the invention provides methods for aiding a prostate cancer diagnosis, which comprises determining a test amount of a marker in a sample from a subject and determining whether the test amount is a diagnostic amount consistent with a diagnosis of prostate cancer (page 2, lines 25-29). With regards to the "test amount", the specification teaches a "test amount of a marker refers to an amount of a marker present in a sample being tested, wherein the test amount can be either in absolute amount or relative amount (page 8, lines 27-29). The specification further teaches (beginning on page 30, Examples) that protein markers were identified using a Ni(II) ProteinChip® Array, H4 ProteinChip® array, and a SCX1 ProteinChip® array, wherein the samples, specifically seminal plasma, were obtained from one BPH (benign prostate hyperplasia) patient and one patient with prostate cancer. With regards to the Ni(II) ProteinChip ® array, the specification teaches (page 30, line 28 to page 32, line 12 and Figure 4) that a number of proteins such as proteins having an apparent molecular weight of about 2776 Da, 4423 Da, 4480 Da,

5753 Da, 6098 Da, 6270 Da, 6998 Da, 8030 Da and 8714 Da, were found to be very abundant in the sample from the prostate cancer patient than in the sample from the BPH patient. Moreover, the specification teaches (page 30, line 28 to page 32, line 12 and Figure 4) that a number of proteins such as proteins having an apparent molecular weight of about 2776 Da, 2905 Da, 3038 Da, 3600 Da, 3835 Da, 3933 Da and 4175 Da, were found to be very abundant in the sample from the BPH patient than a sample from the prostate cancer patient. With regards to the H4 ProteinChip ® array, the specification teaches (page 32, line 15 to page 33, line 23, and Figure 5) that a number of proteins such as proteins having an apparent molecular weight of about 2776 Da, 5753 Da, 6098 Da, 6270 Da, 6998 Da, 7843 Da, 8030 Da and 8240 Da were found to be very abundant in the sample from the prostate cancer patient than the samples from the BPH patient. Furthermore, the specification teaches (page 32, line 15 to page 33, line 23, and Figure 5) that a number of proteins such as proteins having an apparent molecular weight of about 2776 Da, 6098 Da, 6270 Da, 6998 Da, 7843 Da and 8030 Da were also bound and detected using the Ni (II) ProteinChip ® array. With regards to SCX1 ProteinChip® array, the specification teaches (page 33, line 25 to page 34, line 23 and Figure 6) that a protein having an apparent molecular weight of about 5753 Da was present at a high level (relative intensity of about 52) in the sample of the prostate cancer patient. Thus, while the specification clearly teaches that a sample obtained from seminal plasma having a protein characterized by a molecular weight of 2776 Da, 4423 Da, 4480 Da, 5753 Da, 6098 Da, 6270 Da, 6998 Da, 7843 Da, 8030 Da, 8240 Da and 8714 Da is a diagnostic of prostate cancer versus benign prostate hyperplasia, the specification appears to be silent on any other proteomic profiles obtained from any sample which can be used for a diagnostic amount consistent with the diagnosis of prostate cancer versus benign prostate hyperplasia.

Quantity of experimentation

The quantity of experimentation in the area of proteomics for diagnosis and/or differentiation of prostate cancer vs. benign prostate hyperplasia is extremely large given the infancy of using this technology for diagnostic purposes.

The unpredictability of the art and the state of the prior art

The state of the art at the time of filing was such that one of skill could recognize the unpredictability of using proteomic profiling in a diagnostic setting. For example, Diamandis, E.P. (J. National Cancer Institute 2004; 96: 353-356, *of record*) discusses the potential problems in the analysis of serum proteomic patterns for early cancer diagnosis. These problems for identifying tumor markers include the mechanisms by which tumor markers are released into the circulation, their abundance in biologic fluids, their metabolism and excretion, their dynamic relationship within the host, the clinical samples used, the mass spectrometry instrument and/or the bioinformatic analysis (page 353, 1st column, 3rd paragraph). For instance, Diamandis teaches that discrepancies in the discriminatory peaks (i.e., peaks representing molecules that appear or disappear during cancer progression, or whose amounts differ in cancerous versus noncancerous tissue) identified by four different papers by three different research groups suggests that serum proteomic patterns obtained by the SELDI-TOF technique may not be reproducible within a group or among groups of investigators for the same type of cancer, even when the general analytical methods or datasets are the same (page 353, 1st column, 4th paragraph). Regarding the clinical samples, Diamandis teaches that it is still unknown whether the proteomic patterns will differ between plasma and serum, or how they are affected by the number of freeze thaw cycles or its length of storage (page 354, 1st column, last paragraph). More recently, Diamandis et al. (Clinical Cancer Research 2005; 11: 963-965, *of record*) teach that while the original papers on serum proteomic profiling for diagnosis of various forms of cancer reported impressive results, these results have not been reproduced by other laboratories and the method has not been validated (page 964, 2nd column, 1st full paragraph). Specifically, Diamandis et al. teach that using peaks of unknown identity for diagnostic purposes should not be a reason a reason to invalidate the method; instead, as Ranshoff points out, it will be important to examine "if this technology does work" and leave the question of "how it works" for investigation at a later time. However, Diamandis points out that precautionary measures about sample collection, processing, and patient selection must be seriously considered to avoid biases (page 964, 2nd column, 1st full paragraph). Along the same lines, Grizzle et al. (Cancer Informatics 2005; 1: 86-97, *of record*) teach that the use of any multiplex mass spectroscopy based approach, as in the analysis of bodily fluids to detect a disease, must be analyzed with great care due to the

susceptibility of multiplex and mass spectroscopy methods to biases introduced via experimental design, patient samples, and/or methodology (abstract). In particular, Grizzle et al. teach that specific biases include those related to experimental design, patients, samples, protein chips, chip reader and spectral analysis (abstract). Regarding the biases based on patients, Grizzle et al. teach that these biases include demographics (e.g., age, race, ethnicity, sex), homeostasis (e.g., fasting, medications, stress, time of sampling), and the site of analysis (hospital, clinic other) (beginning on page 88, 2nd column to page 92, 1st column). Regarding the biases in samples, Grizzle et al. teach that the biases in samples include conditions of sampling (type of sample container, time of processing, time to storage), conditions of storage (time and temperature of storage), and prior manipulation (freeze thaw cycles)(beginning on page 92, 1st column to page 93, 1st column), experimental design, patient samples, and/or methodology (abstract). These references demonstrate that there are a number of different biases that need to be considered prior to providing a diagnosis of a diseases based on proteomic profiling.

Conclusion

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the lack of guidance provided in the specification for correlation in vitro results to in vivo success, and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as written.

In response to this rejection, Applicants assert that the pending claims are directed to distinguishing between prostate cancer and BPH by using MS to profile samples for low molecular weight markers, wherein the markers making up the profiles may be individually unidentified and require undue experimentation to identify. However, Applicants assert that this irrelevant truth does not mean that applicants have failed to teach how to make and use the method as claimed without undue experimentation. For example, Applicants assert that the non-enabled protein markers of use in the invention are not a part of the inventive principle of the claims and thus do not require enablement beyond demonstration that adequate numbers of protein are routinely detectable using MS for those to practice the claims. Moreover, Applicants assert that the decisional law for written description apply with equal force to enablement. For instance, Applicants contend that if a

hypothetical claim reads on genes defined by what they do rather than what they are structurally, that claim will fail both description and enablement aspects of 112. However, Applicants contend that the fact that it is not possible to set forth all protein markers in a given sample resulting from increased PSA activity does not render the pending clams non-enabled or that sample "handling" might cause problems is not a legally sufficient basis to reject the pending claims. Applicants further assert that this invention is more of a bioinformational-type invention and not a chemistry/composition invention and point out that the current amendments to claim 1 are intended to address the concerns of the Examiner regarding claims reading on using MS to detect unknown markers. Thus, Applicants submit that it is irrelevant that there are dozens of different adjustable parameters that theoretically affect the dynamic range of any MS device for detecting low molecular weight proteins resulting from over expression of PSA. Instead, Applicants assert that what is relevant is that these markers are detectable using MS, and MS is a tool that does not require any express identification of specific markers because it works by mass profiles and is not focused on the primary amino acid sequences of individual markers. Lastly, Applicants assert that the methods of profiling low molecular weight proteins in samples using MS are well known and the inventive principle is in the application of well-known methods to new samples, and the methods for practice are thoroughly taught in the specification. Secondly, regarding Applicants assertions that the decisional law for written description apply with equal force to enablement, the Examiner recognizes that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115). As such, any arguments pertaining to equating the written description to enablement has not been considered.

These arguments have been carefully considered, but are not found persuasive.

First, regarding Applicants assertions with respect to the pending claims, the Examiner acknowledges that the current claims are directed to using MS to profile samples for low molecular weight markers, e.g., inventive principle, for the purpose of distinguishing between prostate cancer and BPH, wherein an increase in the quantity of lower molecular weight proteins is indicative of prostate cancer. However, in contrast to Applicants assertions that the non-enabled protein markers are not a part of the inventive principle of the claims, e.g., are irrelevant, and do not require enablement, the Examiner recognizes that, as stated on page 3 of the Yip declaration filed on 6/26/2006, "The successful use of the prostate classification system described herein relies on the

protein fingerprinting of the nine masses. Because these masses were found to be reproducibly reliably detected...." (*Emphasis added*) In other words, while the "inventive principle" uses mass spectroscopy to profile samples, success, e.g., reproducibility, is dependent on the use of the nine protein masses, and not merely the quantity of a plurality of protein markers in a sample. Moreover, the claims encompass determining by mass spectroscopy a representative pattern of the quantity of a plurality of protein markers in a sample, the protein markers having an apparent molecular weight of less than 10,000 Da and comparing the patter of the plurality of protein markers having an apparent molecular weight of less than 10,000 Da with an amount of a plurality of protein markers having an apparent molecular weight of less than 10,000 Da from a control sample where the control sample originates from benign prostate hyperplasia and determining whether the pattern of the sample is a diagnostic amount consistent with a diagnosis of prostate cancer versus benign prostate hyperplasia where the pattern consistent with a diagnosis of prostate cancer is represented by an increase in the quantity of lower molecular weight proteins. Thus, the claims encompass any patient, which could be a normal patient, and any sample. However, while the specification has taught a comparison of mass values between patients suffering from prostate cancer and BPH, the specification has not taught any mass values obtained from a "control", e.g., a normal patient. Moreover, while the specification has taught a number of mass values obtained from a prostate cancer patient's seminal plasma, these mass values do not appear to be identical or reproducible from the mass values obtained from Adam's serum samples or Cazares et al.'s prostate tissues samples. As such, one of skill would need to first identify mass values from prostate tissue, blood, serum, semen, seminal fluid or seminal plasma, which are reproducibly reliably, detected from each of these samples and than use these mass values for classification and diagnosis. Thus, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as written.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is

either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 8, 12, 20 and 84-94 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 1-14 of copending Application No. 10/221,905.

Although the conflicting claims are not identical, they are not patentably distinct from each other because a species anticipates a genus. For example, the specific protein markers having a molecular weight of 97402.68, 9752.30, 8766.93, 6277.97, or 2781.72 Da claimed in the conflicting application anticipates the genus of a markers having an apparent molecular weight of less than 10,000 Da claimed in the application being examined.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response to this rejection, Applicants assert that they believe that the subject application will be the first to issue and reserve the right to file a terminal disclaimer at the appropriate time during prosecution of the 905 application.

Thus, the rejection of Claims 1, 8, 12, 20 and 84-94 as being provisionally rejected on the ground of nonstatutory obviousness-type double patenting is maintained.

Claims 1, 8, 12, 20 and 84-94 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 1-8 of copending Application No. 10/505,367.

Although the conflicting claims are not identical, they are not patentably distinct from each other because a species anticipates a genus. For example, the specific protein markers having a

molecular weight of 3448, 4036, ... 8445 Da claimed in the conflicting application anticipates the genus of a markers having an apparent molecular weight of less than 10,000 Da claimed in the application being examined.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 8, 12, 20 and 84-94 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 91-109 of copending Application No. 10/513,649.

Although the conflicting claims are not identical, they are not patentably distinct from each other because a species anticipates a genus. For example, the specific protein markers having a molecular weight of 4475, 5074, 5382, ... 9656 Da claimed in the conflicting application anticipates the genus of a markers having an apparent molecular weight of less than 10,000 Da claimed in the application being examined.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Therefore, NO claim is allowed

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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